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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,691	04/14/2004	Steven J. Soldin	31603-2053	5360
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TORYS LLP 79 WELLINGTON ST. WEST SUITE 3000 TORONTO, ON M5K 1N2 CANADA			EXAMINER WALLENHORST, MAUREEN	
			ART UNIT 1743	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/823,691

Applicant(s)

SOLDIN, STEVEN J.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication; even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/30/06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application
- ☐ Other: ____

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1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprise" and "comprising". Correction is required. See MPEP § 608.01(b).
3. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since the preamble of the claim recites a sample "possibly containing one or more steroid hormones", which indicates that the sample may not contain any steroid hormones therein; whereas part (a) of claim 1 positively recites that the sample does contain one or more steroid hormones. Therefore, the preamble and part (a) of claim 1 are not commensurate in scope with one another. See this same problem in claims 27, 28 and 30.

In claim 12, the phrase "the column" lacks antecedent basis.

4. Claims 32-33 provides for the use of a mass spectrometer, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claims 32-33 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6, 9-10, 12-16, 18, 21, 24, 26-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kissmeyer et al (article submitted in the Information Disclosure Statement (IDS) filed on November 30, 2006).

Kissmeyer et al teach of a method and system for determining vitamin D analogs in human and pig serum using liquid chromatography-tandem mass spectrometry. An internal standard is used to spike samples of 1.0 ml of serum. Proteins in the spiked samples are precipitated using two volumes of acetonitrile. After centrifugation, the samples are loaded onto a C18 reversed phase liquid chromatography column. Mass spectrometry is performed on a PE/Sciex API 3000 Mass Spectrometer. The ion source is operated in positive electrospray ionization mode. See the abstract and experimental section on pages 118-120 of Kissmeyer et al. Since the instant claims recite analyzing a sample “containing **one** or more steroid hormones”,

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the teaching of Kissmeyer et al, which analyzes a vitamin D analog in a serum sample, anticipates instant claims 1-3, 6, 9-10, 12-16, 18, 21, 24, 26-29 and 32-33.

7. Claims 1-3, 8-10, 12, 14-16, 18, 21, 24, 26-29 and 32-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Jonsson et al (article submitted in the IDS filed on November 30, 2006).

Jonsson et al teach of a method and system for the determination of cortisol in saliva samples using liquid chromatography-electrospray tandem mass spectrometry. Saliva samples are spiked with a deuterium-labeled internal standard. Proteins are precipitated using acetonitrile, and then centrifuged. After centrifugation, the supernatant is applied to a C8 column. Mass spectrometry is performed on an API 3000 LC-MS-MS. See the abstract and experimental section on pages 64-65 of Jonsson et al. Since the instant claims recite analyzing a sample "containing **one** or more steroid hormones", the teaching of Jonsson et al, which analyzes cortisol in a saliva sample, anticipates instant claims 1-3, 8-10, 12, 14-16, 18, 21, 24, 26-29 and 32-33.

8. Claims 1-4, 6, 9, 12-16, 18, 21, 23, 25, 27-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kao et al (WO 01/88548, submitted in the IDS filed on November 30, 2006).

Kao et al teach of a method and system for simultaneously analyzing at least three components of the adrenal pathway using LC-tandem mass spectrometry. The samples can be blood or serum samples, and the adrenal pathway components can be progesterone, 17-hydroxyprogesterone, dehydroepiandrosterone, cortisol and 11-deoxycortisol. Samples are spiked with an internal standard, and proteins are then removed from the samples by extraction

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using methylene chloride. The samples are applied to a C18 column, and the steroid hormones are detected on an API 2000 mass spectrometer, operated in the multiple reaction-monitoring mode. All results are generated in the positive ion mode. See pages 2, 7 and 9-10 of Kao et al.

9. Claims 1-6, 9, 12, 14-16, 18, 22, 24, 26-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Fredline et al (article submitted in the IDS filed on November 30, 2006).

Fredline et al teach of a method and system for the determination of aldosterone in samples of plasma or blood. Aliquots of 2 ml are extracted and deproteinated with dichloromethane/diethyl ether, containing an internal standard. The sample is applied to a liquid chromatography system and analyzed using a tandem mass spectrometer in a selected reaction-monitoring mode. An atmospheric pressure chemical ionization interface is used in a negative ionization mode. See the abstract and pages 309-310 of Fredline et al. Since the instant claims recite analyzing a sample "containing **one** or more steroid hormones", the teaching of Fredline et al, which analyzes aldosterone in a blood or plasma sample, anticipates instant claims 1-6, 9, 12, 14-16, 18, 22, 24, 26-29 and 32-33.

10. Claims 1-3, 7, 9, 12-21, 23, 25, 27-29 and 32-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Leinonen et al (article submitted in the IDS filed on November 30, 2006).

Leinonen et al teach of a method and system for analyzing anabolic steroids in urine using LC-mass spectrometry. The buffered samples are extracted and deproteinated using diethyl ether. Samples are applied to a C18 reversed phase chromatography system and investigated using mass spectrometry. Three different modes of ionization are used: electrospray ionization, atmospheric pressure chemical ionization and atmospheric pressure photoionization.

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All measurements are performed in the positive ion mode. Test samples containing several steroids are investigated. See the abstract and pages 694-695 in Leinonen et al.

11. Claims 1-3, 6, 11-16, 18, 21, 23, 26-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Vogeser et al (article submitted in the IDS filed on November 30, 2006).

Vogeser et al teach of a method and system for determining cortisol in serum samples. Serum samples are precipitated with a methanol/zinc sulfate solution containing deuterated cortisol as an internal standard. After vortexing, the samples are centrifuged and subject to HPLC chromatography on a C18 column. Figure 1 shows a column-switching scheme for an online extraction procedure. Electrospray atmospheric pressure ionization mass spectrometry in the positive mode is used. Multiple reaction monitoring is used. See the abstract and pages 944-945 of Vogeser et al. Since the instant claims recite analyzing a sample "containing **one** or more steroid hormones", the teaching of Vogeser et al, which analyzes cortisol in a serum sample, anticipates instant claims 1-3, 6, 11-16, 18, 21, 23, 26-29 and 32-33.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Kissmeyer et al, Jonsson et al, Kao et al, Fredline et al, Leinonen et al or Vogeser et al. For a teaching of Kissmeyer et al, Jonsson et al, Kao et al, Fredline et al, Leinonen et al and Vogeser et al, see previous paragraphs in this Office action.

Each of Kissmeyer et al, Jonsson et al, Kao et al, Fredline et al, Leinonen et al and Vogeser et al fail to teach of incorporating all of the needed/required reagents and instrumentation for analyzing steroid hormones in a biological sample into a kit form. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate all of the needed/required reagents and instrumentation required for analyzing steroid hormones in accordance with the methods taught by any one of Kissmeyer et al, Jonsson et al, Kao et al, Fredline et al, Leinonen et al or Vogeser et al in a kit form so as to make the methods more convenient and easy to perform by having all of the necessary components in one centralized location, thus facilitating the quick and efficient analysis of steroid hormones without having to take extra time to assemble the various reagents and instrumentation required.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kissmeyer et al (article from the Journal of Chromatography), Dooley and Gao who all teach of different methods for determining steroid hormones in biological samples.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

April 23, 2007

Maureen M. Wallenhorst
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